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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,609	01/17/2002	Brian Lauman	DI-5764 (112713-146)	1135
29200	7590	12/01/2005	EXAMINER	
BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/051,609

Applicant(s)

LAUMAN ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 37-52 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-12 is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-36 and 53-55 is/are rejected.
- 7) ☒ Claim(s) 1 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the enclosure housing a pump or radiant heater or secondary heater or disposable cassette as recited in claims 1, 13, 14, 18, 23, 27, and 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for an enclosure, or for an enclosure housing a pump and/or heaters.

### ***Claim Objections***

Claims 1 and 10 are objected to because of the following informalities: it appears there is a typographical error by writing “infrared” heater instead of “radiant” heater in claim 1 and writing claim “8” instead of claim “9” in claim 10. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 13, 14, 18, 23, 27, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite an enclosure housing a pump and/or housing heaters or an enclosure configured to removably accept a disposable unit. This arrangement of enclosure, pump, heaters, and/or disposable unit is not found in the specification as filed.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, 6, 7, 30, 31, 32, 34, 35, 36, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by HICKERSON et al. (US Pub. No. 2003/0004470). Hickerson discloses a medical fluid heater comprising an enclosure housing a pump and individually controlled radiant plate heaters 6 (Para. 0009, 0019, 0021, 0037). The heaters are considered plate heaters because of their flat wide profile. Radiant energy emitted from the inductive heaters heat the fluid flowing through a removable cassette 19. Air and cassette fluid housing are transmissive materials located between the heater and fluid. The position of the heaters 6 place them upstream and downstream of the fluid flowing through the cassette. Temperature sensors are employed to achieve the desired amount of heating (0010, 0034). The fluid flow container is operable with a valve (0010) and is connected to a bulk dialysis fluid container 14 and a catheter 25.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 14, 15, 16, 17, 23, 24, 25, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over HICKERSON as applied to claim 1 above, and further in view of KAMIYAMA et al. (US Patent No. 5,271,086) and GORDON (US Patent No. 6,261,261). Hickerson discloses the claimed invention except for using an infrared heater with other heaters. Hickerson does disclose various heater that could be used to supply the heating energy, including ceramic heaters (0037), but does not specifically state an infrared emitter or reflectors. Hickerson does not disclose infrared transmitters of quartz. Kamiyama teaches the use of infrared ceramic heaters to heat fluids and infrared transmitter of quartz to aid in supporting the heater. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kamiyama in the device of Hickerson to employ various heater types to obtain heaters to work under different conditions. The use of different heater types is suggested by Hickerson to achieve various desired goals, such as minimizing energy loss, energy storage, or fast initial warm-up (0037). Gordon teaches the use of infrared reflectors to achieve heating (fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gordon in the device of Hickerson and Kamiyama to achieve efficient heating. Re claims 15 and 16 placing the infrared heater adjacent the same or different parts of the cassette would be a design choice. With regards to claims 23 and 24 Hickerson is silent

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concerning achievable flow and heat rates, but it is obvious the disclosed device would be capable of achieving heating the claimed flow rate and heating rate because Hickerson discloses that the device can heat from cold temperatures to patient temperature and the claimed flow rate is a typical dialysis flow rate.

Claims 18, 19, 20, 22, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over HICKERSON in view of MULLER (GB 2 242 367) and GORDON. Hickerson discloses the claimed invention as discussed above except for an infrared bulb to assist in heating or reflective surface. Muller teaches the use of an infrared bulb to heat fluids. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Muller in the device of Hickerson to achieve various heating profiles with different heaters. With regards to claim 19 Hickerson is silent concerning achievable flow and heat rates, but it is obvious the disclosed device would be capable of achieving heating the claimed flow rate and heating rate because Hickerson discloses that the device can heat from cold temperatures to patient temperature and the claimed flow rate is a typical dialysis flow rate. Gordon teaches the use of infrared reflectors to achieve heating (fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gordon in the device of Hickerson and Muller to achieve efficient heating. Re claim 55 the claimed limitations would be obvious design choice for an infrared bulb, and applicant has not stated that the claimed limitations are for a particular purpose or to solve a stated problem and it appears that other infrared bulb characteristics would work equally as well.

Claims 13 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over HICKERSON in view of GORDON. Hickerson discloses a housing for a fluid pump and

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controllable heaters to heat fluid to a desired temperature. Hickerson does not disclose the heaters to be two plate infrared emitters. Gordon discloses the use of two plate infrared heaters 30a, b to achieve heating of IV solutions and absorption material 102. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gordon in the device of Hickerson to efficiently prewarm solutions before administering them to a patient.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over HICKERSON in view of FORD (EP 0 575 512). Hickerson discloses the claimed invention except for collecting gas from the dialysis fluid. Ford teaches using a bubble trap to collect gas from the heated fluid. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ford in the device of Hickerson in order to eliminate bubbles.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-32 and 53-55 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

Claims 8-12 are allowed.



*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons, can be contacted at (571) 272-4965. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh

28 November 2005

A handwritten signature in black ink, appearing to read "M. J. Hayes", with a stylized flourish at the end.

**MICHAEL J. HAYES  
PRIMARY EXAMINER**